

149646

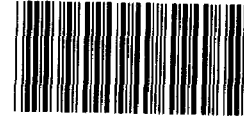


United States  
General Accounting Office  
Washington, D.C. 20548

Resources, Community, and  
Economic Development Division

B-253771

July 15, 1993



149646

The Honorable Harold L. Volkmer  
Chairman, Subcommittee on Livestock  
Committee on Agriculture  
House of Representatives

This letter responds to your request for information on (1) inspection and testing standards for dairy products in the United States and selected foreign countries, (2) any different standards or requirements that could potentially impede the free trade of dairy products, and (3) any such standards being considered by the member nations of the General Agreement on Tariffs and Trade (GATT).

In summary, we found that inspection and testing standards for dairy products varied among the seven countries we reviewed.<sup>1</sup> Unlike the United States, most countries do not inspect dairy farms or plants or test dairy products at intervals specified in national laws or regulations. Instead, they base the frequency of their inspection and testing on the resources available and on potential problems that have been identified. Some countries delegate the responsibility for inspection and testing to state or local governments.

We found no evidence that countries were using inspection and testing or other health and safety standards to impede free trade. Currently, the primary barriers to free trade in dairy products are economic quotas and tariffs. However, while health and safety standards are not currently being used as trade barriers, differences in health and safety requirements could potentially impede the free trade of dairy products in the future. For example, (1) the European Community's new unified inspection provisions could prove difficult for the United States to meet because they require that inspections be conducted by

<sup>1</sup>The seven countries were the United States, Canada, France, Italy, Japan, Mexico, and New Zealand.

058610/149646

veterinarians; (2) the United States' engineering standards for dairy plants could be used to impede imports because the standards require equipment, such as flow diversion devices on pasteurizers, that are frequently absent in foreign plants; and (3) some countries' labeling requirements, such as those requiring production dates, could put foreign products at a competitive disadvantage.

The foreign countries we visited had no specific proposals for incorporating inspection and testing standards into the GATT or the standards developed by the Codex Alimentarius Commission (CODEX).<sup>2</sup> The final draft of the GATT does not specify safety standards for dairy products, but refers to the CODEX standards, among others. Although the CODEX standards include definitions for some dairy products, they do not specify inspection and testing requirements. However, FDA and CODEX officials told us that they view the GATT and the CODEX standards as encouraging countries to base food import requirements on scientific and health-related considerations.

#### BACKGROUND

Under the Federal Food, Drug, and Cosmetic Act, as amended, the Food and Drug Administration (FDA) has primary responsibility for ensuring that domestic and imported dairy products meet federal standards. These standards require that the products be safe, pure, wholesome, and accurately labeled. The safety of domestic dairy products is ensured through inspections of raw materials and processing facilities, the use of good manufacturing practices by the producers, and some sampling and testing of raw materials and finished products. Multiple agencies, including FDA, state agencies, and the U.S. Department of Agriculture (USDA), have various roles in ensuring the safety of dairy products.

FDA is solely responsible for regulatory oversight of the safety of imported dairy products. For all imported dairy products, FDA samples and tests finished products to ensure

---

<sup>2</sup>The Codex Alimentarius Commission, established in 1963 as a subsidiary body of the Food and Agriculture Organization of the United Nations and the World Health Organization, has developed a compilation of food standards to facilitate fair trade in food while protecting the health of consumers. Codex alimentarius is Latin for food code.

that they meet federal standards. In addition, before fresh or frozen milk or cream can be imported into the United States, FDA is required by the Federal Import Milk Act (21 U.S.C. 141-149) to ensure, through inspections or through certification of the exporting country, that these products are properly produced and handled. According to the head of FDA's Milk Safety Branch, New Zealand is currently the only country approved to export fresh or frozen milk or cream to the United States. The official said that the United States has never denied certification to any country requesting it and, of the countries we visited, New Zealand was the only one that had asked for certification. FDA approved the importation of frozen cream from New Zealand without inspecting its dairies. Instead, FDA relies on the New Zealand government's certification that the frozen cream meets all the requirements of the Federal Import Milk Act.

#### INSPECTION AND TESTING STANDARDS VARY

While the United States and New Zealand have specific inspection and testing requirements and frequencies, the other countries included in our review do not. (An enclosure summarizes each country's program.) Dairy inspection and testing requirements and frequencies vary among and within these countries according to the (1) resources available and (2) health risks and concerns associated with the products. For example, countries may choose to devote resources to testing for listeria (a bacterium that causes encephalitis) in unpasteurized dairy products.

In the United States, dairy farms must be inspected twice a year and dairy processing plants must be inspected four times a year under the Pasteurized Milk Ordinance (PMO), a cooperative agreement among the states. These inspections are performed by the states, subject to periodic evaluations by FDA dairy program officials. FDA officials evaluate state inspections by inspecting dairy farms at least once every 4 years and dairy plants at least once every 3 years.

The PMO also requires that raw milk be sampled at the farm four times every 6 months and that every tanker truckload of milk delivered to a dairy plant be sampled. At dairy plants, each type of processed product must be sampled at least four times every 6 months.

Samples from the farms and tankers are tested for bacteria levels (measured by a "standard plate count"), animal drug residues, and the level of somatic cells (animal cells for which an elevated count indicates infection in the cow). At dairy plants, samples of finished products are tested for bacteria levels, animal drug residues, coliform (which indicates fecal contamination), and phosphatase (elevated levels of which indicate inadequate pasteurization). Water supplies at farms and dairy plants are also periodically sampled and tested for coliform.

Dairy farms or plants that fail to pass inspections or perform required tests can be removed from the Interstate Milk Shippers' list. Dairy plants must be included on this list to sell their products in interstate commerce or to any other listed dairy plant. Furthermore, plants must be included on the list to sell class-A dairy products like milk, cream, whipping cream, and half-and-half.

New Zealand also specifies inspection frequencies, but its approach is somewhat different. Dairy farms must be inspected from one to three times a year, depending on the category of the farm.<sup>3</sup> A-level farms are inspected annually, B-level farms are inspected 3 times a year, and C-level farms are inspected 12 times a year. Dairy plants must also be inspected at least three times a year.

In New Zealand, dairy farms and plants are inspected, at their own expense, by government-certified third parties. New Zealand government inspectors make oversight inspections of each dairy farm and dairy plant at least annually. While these inspections ensure that operations at the farms and plants comply with New Zealand's regulations, their main purpose is to evaluate the third-party inspections.

New Zealand, like the United States, also specifies testing requirements and frequencies. Raw milk at the farm must be

---

<sup>3</sup>According to New Zealand's Chief Dairy Officer, farms are placed in categories according to the results of standard microbiological plate counts. Products from A-level farms have a standard plate count of less than 100,000; from B-level farms, less than 200,000; and from C-level farms, in excess of 200,000. Most New Zealand dairy farms are categorized as A-level farms because their products have a standard plate count of about 50,000.

tested every 10 days for bacterial levels, animal drug residues, water content, and somatic cell levels. At dairy plants, at least four lots of each product type are sampled each month. One sample from each lot undergoes chemical analysis and one sample undergoes microbiological analysis. Chemical analysis includes testing for trace metals, nitrates and nitrites, and pesticides. Microbiological analysis includes testing for salmonella and listeria.

The other five countries we reviewed--Canada, France, Italy, Japan, and Mexico--have not set specific inspection or testing frequencies for their dairy farms or plants. Instead, some of these countries base the frequency of such activities on the resources available and on potential or identified problems. Others delegate such responsibilities to state or local governments. For example, Italian government officials said their goal is to inspect each dairy plant annually, but the actual frequency of inspections varies according to the risk the product presents and the funds and staff available to the local health offices that perform the inspections. Canada, instead of formally setting a testing frequency for all finished dairy products, bases testing frequency on the individual products and the potential risk they present.

THERE IS NO EVIDENCE THAT NONECONOMIC TRADE BARRIERS ARE USED, BUT THE POTENTIAL EXISTS

According to the Foreign Agricultural Service's 1990 report Trade Policies and Market Opportunities for U.S. Farm Exports, economic quotas and tariffs are the primary barriers to the free trade of dairy products. While we found no evidence of the use of noneconomic trade barriers, the potential for their use may increase following the pending expansion of the GATT and the associated elimination of economic trade barriers. Differences in inspection procedures, plant engineering standards, and labeling requirements--although not currently used as trade barriers--could potentially be used as such in the future.

Inspection Procedures Differ

The 12-member European Community (EC)<sup>4</sup> intends to improve its competitiveness by abolishing barriers to trade among its members. EC directive 92-46, effective January 1, 1994, sets forth rules for the production and marketing of dairy products. According to EC officials, the directive requires the EC to approve each member country's system for inspecting and testing milk and dairy products to ensure that these requirements are met. Once a country's system has been approved, all dairy products from that country will carry a health certificate showing they are from an approved plant. These products can then be traded freely throughout the community.

Under the directive, the EC can also certify non-EC countries, referred to as third countries, to trade within the community. Certification requires both technical and political approval. That is, certification will be granted if (1) the country is deemed to have an oversight system equivalent to the EC system and (2) the EC member nations agree. Once a third country is certified, all dairy plants within that country will be allowed to trade with EC countries. Dairy plants in countries that are not certified will have to undergo individual inspection and certification by EC inspectors in order to export products to EC member countries.

According to EC officials, the directive requires that the inspectors of dairy farms and plants be veterinarians. In the United States, FDA and state inspectors are generally public health specialists, food technologists, or biologists--not veterinarians. As a result, the EC could conclude that the U.S. system is not equivalent and therefore require that each U.S. dairy plant that desires export privileges undergo an EC inspection. The frequency of equivalency reviews and individual plant inspections under the directive has not yet been determined.

Plant Engineering Standards Differ

Engineering standards for dairy plant equipment also vary among the countries we reviewed. U.S. engineering

---

<sup>4</sup>The EC member countries are Belgium, Denmark, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, and the United Kingdom.

standards, designed to prevent product contamination during processing or when processing equipment breaks down, were generally absent in foreign dairy plants we visited. The United States could decide to exclude products from countries whose plants do not meet the U.S. standards.

To ensure safe, wholesome dairy products, U.S. dairy plants must meet the following design standards, among others:

- Pasteurization holding tubes must have a continuous rise in elevation of 1/4 inch per linear foot.
- Pump speeds and time and temperature settings for pasteurizers must be set and officially sealed by state inspectors to ensure that the proper time and temperature are used. Broken seals alert state inspectors that the equipment settings may have been changed.
- Flow diversion devices that automatically recycle products through the pasteurizer if they did not reach adequate pasteurization temperature are required.
- Pumps are not allowed downstream from the flow diversion device on the pasteurizer unless there are appropriate vacuum breakers. Vacuum breakers allow air into the system so that the product is not pulled through the pasteurizer too fast to meet the time and temperature requirements for pasteurization.
- Records from the pasteurizer's 12-hour recorder controller, which show the time, temperature, and position of the flow diversion valve (i.e., whether the valve is open or closed), must be retained and made available for inspection.

In five of the six foreign countries in our review, the dairy plants we visited did not meet all of the U.S. engineering standards mentioned above. (We were not able to observe or verify through other means the dairy plant engineering standards in the sixth country.) Dairy plants in two of the five countries did not meet any of the standards, while the plants in three countries met some but not all of the standards.

Product Labeling Requirements Differ

Variations in standards for product labeling may provide the opportunity for countries to use these standards to create trade barriers. The following two examples illustrate these variations.

First, "yogurt" is defined differently in France, Japan, and the United States. Products must meet different standards of identity before they can be labeled as yogurt in these countries. In France, yogurt must contain two active (i.e., live) bacterial cultures. In Japan, yogurt must contain one active culture of not less than 10 million bacteria per milliliter. In the United States, active bacterial cultures are not required in yogurt. As a result, France, for example, could refuse to import U.S. and Japanese products labeled as yogurt, because they do not meet the French standard of identity for yogurt.

Second, CODEX labeling standards, for example, allow the use of the production date, minimum durability date (frequently referred to as the "best-if-used-by" date), or "sell-by" date on yogurt products. Many consumers interpret the sell-by date and best-if-used-by date as the last day the product should be consumed. In the United States, distributors generally remove products from market shelves once these dates have passed.

Japan, as allowed by the CODEX standards, requires some dairy product labels, such as yogurt labels, to carry the date the product was produced or manufactured. Japanese officials said that Japanese consumers, who demand fresh products, use the production date as an indicator of freshness.

Because of the time required to ship U.S. products to Japan, U.S. products will likely carry a production date that is earlier than the date on their Japanese competitors' products. Given the Japanese consumers' interest in freshness, requiring the production date on the product label puts U.S. dairy products imported into Japan at a competitive disadvantage.

THE GATT DOES NOT SET SPECIFIC  
INSPECTION AND TESTING STANDARDS

Harmonizing the food safety regulations and requirements of the member nations is one of the objectives of the GATT.



However, given the difficulty of obtaining the agreement of all GATT signatories, the draft of the final agreement does not contain specific food safety standards but instead refers to, among others, the CODEX standards.

Government officials in the countries we visited all supported the CODEX standards. Although they may consider particular CODEX standards as unreasonable, they generally viewed them as minimum standards, which each GATT member nation may augment as desired. Although CODEX permits countries to augment the standards, FDA and CODEX officials told us that they view the GATT and the CODEX standards as encouraging countries to base food import standards on scientific and health-related considerations.

The CODEX standards include general standards for hygiene, labeling, and additives as well as specific standards for the various commodities. Dairy products are covered in volume XVI of the CODEX standards, entitled Code of Principles Concerning Milk and Milk Products, International Standards for Milk Products and International Individual Standards for Cheeses. The standards set in this volume for cream powder, half-cream powder, and high-fat milk powder include

- product definitions;
- essential composition and quality factors, such as the percentage of milk fat required and the maximum water content;
- permitted food additives, such as stabilizers and emulsifiers; and
- specific dairy product labeling requirements that augment CODEX's general labeling requirements.

While CODEX has not set inspection and testing standards for dairy plants and products, CODEX officials said that the frequency of inspections will be addressed in the future. The CODEX committee on dairy products--the committee with the continuing responsibility for drafting CODEX international codes and standards for milk and milk products--is tentatively scheduled to meet in the second half of 1994.

SCOPE AND METHODOLOGY

To determine inspection and testing frequencies for dairy products in the United States, we interviewed cognizant officials at FDA headquarters in Washington, D.C., and its Western Region office in San Francisco. We interviewed California officials responsible for dairy plant inspections and observed federal and state inspections at California dairy plants. We also obtained and reviewed pertinent federal dairy regulations and studies.

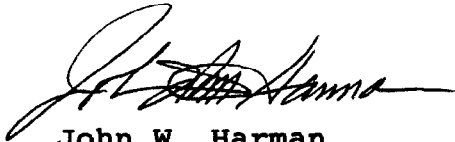
To determine inspection and testing frequencies in foreign countries, we visited three foreign countries--France, Italy, and New Zealand--that were major suppliers of dairy products to the United States and three foreign countries--Canada, Japan, and Mexico--that were major customers for U.S. dairy products. In these countries, we interviewed (1) government officials responsible for regulating and inspecting dairy farms and dairy plants, (2) dairy industry representatives, (3) import and export brokers for dairy products, and (4) representatives of consumer advocacy or protection groups. We also toured a dairy plant in each country. However, in Japan and New Zealand, plant or government safety regulations restricted us to specific viewing areas and prevented us from observing some key engineering aspects of these plants. We performed limited verifications of the information provided to us in interviews, but we obtained, whenever possible, English translations of the host countries' dairy inspection and testing regulations. However, we cannot fully ensure the accuracy of the information we obtained from language interpreters and translators.

To determine what dairy inspection and testing standards are being considered by the GATT member nations, we interviewed CODEX officials in Rome and European Community officials in Brussels. In addition, we met with government officials cognizant of GATT and CODEX dairy standards in the seven countries included in our review.

- - - - -

B-253771

Major contributors to this report were Edward M. Zadjura, Assistant Director, Resources, Community, and Economic Development Division, and Keith W. Oleson, Evaluator-in-Charge, San Francisco Regional Office. If you have any questions about this information, please contact me at (202) 512-5138.



John W. Harman  
Director, Food and  
Agriculture Issues

Enclosure

DAIRY INSPECTION AND TESTING REQUIREMENTS IN THE UNITED STATES AND SELECTED FOREIGN COUNTRIES

Table 1: Inspection Requirements

Country	Farm inspections	Plant inspections
United States	2 per year	4 per year
Canada	Delegated to provinces <sup>a</sup> --frequency varies	Delegated to provinces--frequency varies
France	No set requirement	No set requirement
Italy	Delegated to local health offices--frequency varies	Delegated to local health offices--frequency varies
Japan	Perfectory <sup>b</sup> responsibility--frequency varies	Perfectory responsibility--frequency varies
Mexico	No set requirement	No set requirement
New Zealand	Varies <sup>c</sup>	3 per year

Note: The information provided was derived from a variety of sources, including national regulations and interviews with cognizant national government officials.

<sup>a</sup>Provinces are regional governments similar to states.

<sup>b</sup>Perfectories are regional governments similar to states.

<sup>c</sup>In New Zealand, inspection and testing frequencies vary with the results of microbial testing: A-level farms--farms whose products have a standard plate count of less than 100,000--are inspected annually; B-level farms--farms whose products have a standard plate count of less than 200,000--are inspected 3 times a year; and C-level farms--farms whose products have a standard plate count in excess of 200,000--are inspected 12 times per year.

Table 2: Testing Requirements

Country	Farm testing	Plant testing
United States	4 tests every 6 months	4 samples of each product every 6 months
Canada	Delegated to provinces--frequency varies	Frequency varies with product type and potential risk
France	Not specified, but at least once per year	Not specified--sampling plan developed each year
Italy	Not required	Not required
Japan	Not required	Not required
Mexico	Not required	Not required
New Zealand	1 test every 10 days	4 samples of every product each month

Note: The information provided was derived from a variety of sources, including national regulations and interviews with cognizant national government officials.

(150614)